

109



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,903	09/17/2003	Stephen J. O'Connor	5062C1	8521

35969 7590 08/25/2004

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EXAMINER

COPPINS, JANET L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/666,903	O'CONNOR ET AL.	
	Examiner	Art Unit	
	Janet L Coppins	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) claims 1-30 in part, wherein Ar is not phenyl is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, in part, 8-15, 17-25, and 28 is/are allowed.
- 6) ☒ Claim(s) 7 and 16 is/are rejected.
- 7) ☒ Claim(s) 26, 27, 29, 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1626

**DETAILED ACTION**

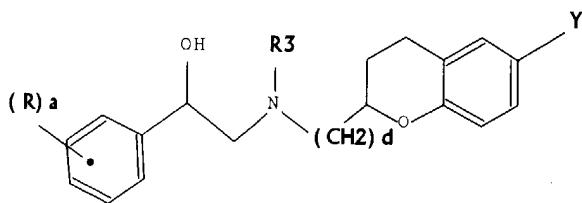
Claims 1 and 11-27 pending in the instant application.

***Information Disclosure Statement***

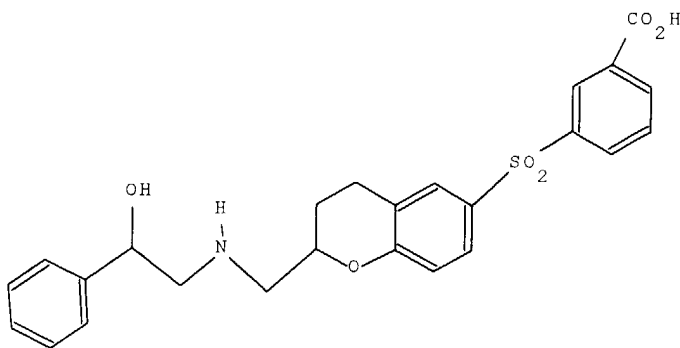
1. Applicants' Information Disclosure Statement (IDS), filed September 17, 2003, has been considered by the Examiner and entered of record in the file. Please refer to Applicants' copy of the 1449 form submitted herewith.

***Response to Restriction/Amendment***

2. Applicants' election of Group I, claims 1-30, drawn to compounds and their pharmaceutical compositions, methods of preparation and methods of use, according to formula (I), wherein Ar is phenyl:



and the specific compound of Example 17:



in the response filed July 8, 2004, is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. It is suggested that in order to advance prosecution, the non-elected subject matter be canceled when responding to this Office Action, i.e. compounds wherein Ar is not phenyl. Applicant is reminded that upon the cancellation of claims or subject matter to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7 and 16 rejected under 35 U.S.C. 112, first paragraph, as being reach-through claims. The claims are directed to a method of treating a beta-3 adrenergic receptor-mediated condition, yet these claims do not meet the requirements for “how to use” under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 101, as stated below. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth below, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 7 and 16 rejected under 35 U.S.C. 101 as being reach-through claims, because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The claimed methods of treating a beta-3 adrenergic receptor-mediated condition does not comply with the utility requirement since there is no disclosed pharmaceutical use, i.e. a method of treating a disease “mediated by the beta-3 adrenergic receptor” is not equivalent to a positive recitation of how to use the product for the treatment of a particular disease of real world relevance. The Examiner suggests incorporating some of the specific diseases that Applicants are enabled for treating, from the specification, or canceling the claims in view of the remaining method claims.

***Claim Objections***

8. Claims 26, 27, 29, and 30 objected to under 37 CFR 1.75 as being substantial duplicates of claims 25 and 28. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Art Unit: 1626

Claim 27 recites a composition comprising an effective amount of a compound of claim 1 in combination with an inert carrier, which is a duplicate of the composition of claim 25.

Claim 30 recites a composition comprising an effective amount of a compound of claim 1 in combination with an inert carrier, which is a duplicate of the composition of claim 28.

Regarding claims 26 and 29, The Examiner would like to remind Applicants that the preambles recite pharmaceutical compositions, and while the use of a descriptive clause, i.e. "for the treatment of...", when referring to the contemplated use (i.e. "intended use") of a claimed compound is proper, it is not a limitation and thus of no significance in determining the patentability thereof over the prior art, please refer to In re Thomas (CCPA 1949) 178 F2d 412, 84 USPQ 132. Therefore, composition claims 26 and 29 are also duplicates of claims 25 and 28, respectively.

#### ***Allowable Subject Matter***

9. Claims 1-6 would appear to be allowable over the prior art if the non-elected subject matter is cancelled from the claims.

10. Claims 8-15, 17-25, and 28 are currently free from the prior art.

#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

Art Unit: 1626

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins

Kamal Saeed  
for Joseph McKane